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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,998	07/10/2003	J. David Rozzell	50704/JDC/B583	8207

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CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,998	ROZZELL ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in this application

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to polypeptide with leucine dehydorgensae, and its mutants, wherein the polypeptide comprises of the amino acid sequences listed in SEQ ID NO: 2 having leucine dehydorgensae activity, classified in class 435, subclass 189.

II. Claim 8, drawn to polynucleotide encoding the polypeptide sequence of group I, classified in class 536, subclass 23.1.

III. Claims 1 and 9-12, drawn to polypeptide with formate dehydorgensae, and its mutants, wherein the polypeptide comprises of the amino acid sequences listed in SEQ ID NO: 1 having formate dehydorgensae, classified in class 435, subclass 189.

IV. Claim 13, drawn to polynucleotide encoding the polypeptide sequence of group II, classified in class 536, subclass 23.1.

V. Claims 1 and 14-17, drawn to polypeptide with galactose oxidase, and its mutants, wherein the polypeptide comprises of the amino acid sequences listed in SEQ ID NO: 3 having galactose oxidase, classified in class 435, subclass 189.

VI. Claim 18, drawn to polynucleotide encoding the polypeptide sequence of group III, classified in class 536, subclass 23.1.

VII. Claim 19, drawn to a method of producing an amino acid that comprises contacting a ketoacid with an amino acid in the presence of a reduced nicotinamide and an ammonia source with the polypeptide of group I, classified in class 435, subclass 106.

VIII. Claim 20, drawn to a method of recycling of a nicotinamide cofactor that comprises contacting an oxidized nicotinamid cofactor in the presence of a formate source with the polypeptide of group III, classified in class 435, subclass 106.

The inventions are distinct, from each other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Invention of groups I through VI, are drawn to products and are patentably distinct from each other. The polypeptide of groups I, III, V and polynucleotide of groups II, IV, VI, each comprise of amino acid sequences and nucleotide sequences which are structurally and functionally unrelated, do not require each other for practice; have separate utilities. For example, use of group I polypeptide to catalyze a reaction or use of group IV polynucleotide in separate hybridization reactions as probes, are subject to separate manufacture and sale.

Inventions of group VII-VIII are drawn to methods and are patentably distinct. Each of the methods or processes has different steps, using different components and modes of operation with different end results. They do not require each other for practice; have separate utilities. For example, the method of production of amino acids in group VII and the method for recycling

nicotinamide cofactor in group VIII involve different and distinct steps and modes of operation. Each requires different kinds of preparation and mode of use and is subject to separate manufacture and sale.

Invention of group I and group VII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of group I can be used to raise specific antibodies, as opposed to its use in the production of amino acids in group VII.

Invention of group II through VI and VII are patentably distinct. The inventions of groups II-VI are products, which are neither used nor made in the method of group VII. They are subject to separate manufacture and sale.

Invention of group III and group VIII are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of group III can be used to raise specific antibodies, as opposed to its use in the method of recycling of nicotinamide cofactor.

Inventions I, II, IV-VI are patentably distinct from group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the inventions in groups I, II, IV-VI are neither used nor made in the method of group VIII for producing cofactors. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Election of Sequence

Applicant is required under 35 U.S.C. 121 and 372 to elect a single appropriate disclosed species i.e., a single SEQ ID NO: associated with the respective group for prosecution on the merits to which the claims are restricted. Note that this is a restriction requirement to sequence and NOT a species election.

MPEP 803.04 states: Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141et seq. It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Examination will be restricted to only the elected group and the elected amino acid /nucleotide sequence.

Hence, the above inventions have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is

advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652
August 26, 2005

MANJUNATH N. RAO, PH.D.
PRIMARY EXAMINER